
42 U.S. Code § 256b

Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the “ceiling price”), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) “Rebate percentage” defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the “rebate percentage” is the amount (expressed as a percentage) equal to—

- (i) the average total rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by
- (ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the “rebate percentage” shall be determined as if the rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) “Over the counter drug” defined

The term “over the counter drug” means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act [42 U.S.C. 1396 et

seq.].

(4) “Covered entity” defined

In this section, the term “covered entity” means an entity that meets the requirements described in paragraph (5) and is one of the following:

- (A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act [42 U.S.C. 1396d(l)(2)(B)]).
- (B) An entity receiving a grant under section 256a^[1] of this title.
- (C) A family planning project receiving a grant or contract under section 300 of this title.
- (D) An entity receiving a grant under subpart II¹ of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).
- (E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.
- (F) A black lung clinic receiving funds under section 937(a) of title 30.
- (G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].
- (H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.
- (I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].
- (J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).
- (K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2)¹ of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).
- (L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)]) that—
 - (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;
 - (ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C. 1395ww(d)(5)(F)(i)(II)]; and
 - (iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.
- (M) A children’s hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)(iii)], or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the

hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act [42 U.S.C. 1395i-4(c)(2)]), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(C)(i)], or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

This document is only available to subscribers. Please log in or purchase access.

[Purchase Login](#)